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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NICKOL, GARY B	
ART UNIT	PAPER NUMBER
1642	29

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/323,597	AFAR ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5 and 32-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2-5, 32-71* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Request for Continued Examination

The request filed on 2-4-02 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/323597 is acceptable and a RCE has been established. Claims 1, and 20-31 were cancelled. Claims 32-71 were added. Claims 2-5 and 32-71 are pending and are currently under prosecution. An action on the RCE follows.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 2-5, drawn to isolated polynucleotides, vectors, and host cells, classified in class 536, subclass 23.1; class 435, subclasses 320.1, 325.

Groups 2-15 have been split based on Claim 32 which is linked to either administering a substance that inhibits the expression of 20P1F12/TMPRSS2 or is linked to administering a substance that inhibits expression of a molecule that is modulated by 20P1F12/TMPRSS2.

2. Claims 32-33, as solely drawn to a method of inhibiting growth of cancer cells by administering a 20P1F12/TMPRSS2-related protein which inhibits the expression of 20P1F12/TMPRSS2, classified in class 424, subclass 184.1.

3. Claims 32, 34-35, as solely drawn to a method of inhibiting growth of cancer cells by administering an antibody or fragment thereof that specifically binds to a 20P1F12/TMPRSS2-related protein which inhibits the expression of 20P1F12/TMPRSS2, classified in class 424, subclass 130.1.

4. Claims 32, 36, as solely drawn to a method of inhibiting growth of cancer cells by administering a vector that comprises a polynucleotide comprising a 20P1F12/TMPRSS2-related protein sequence which inhibits the expression of 20P1F12/TMPRSS2, classified in class 424, subclass 93.2.

5. Claims 32, 37, as solely drawn to a method of inhibiting growth of cancer cells by administering a vector that comprises a polynucleotide comprising an antisense polynucleotide complementary to a polynucleotide having a 20P1F12/TMPRSS2-coding sequence which inhibits the expression of 20P1F12/TMPRSS2, classified in class 514, subclass 44.

6. Claims 32, 38, as solely drawn to a method of inhibiting growth of cancer cells by administering a ribozyme that cleaves a polynucleotide having a 20P1F12/TMPRSS2-coding sequence which inhibits the expression of 20P1F12/TMPRSS2, classified in class 424, subclass 94.1.

7. Claims 32-33, 39, as solely drawn to a method of inhibiting growth of cancer cells by administering at least one CTL epitope of 20P1F12 which inhibits the expression of 20P1F12/TMPRSS2, classified in class 424, subclass 184.1.

8. Claims 32-33, 40, as solely drawn to a method of inhibiting growth of cancer cells by administering at least one antibody epitope of 20P1F12 which inhibits the expression of 20P1F12/TMPRSS2, classified in class 424, subclass 184.1.

9. Claims 32-33, as solely drawn to a method of inhibiting growth of cancer cells by administering a 20P1F12/TMPRSS2-related protein which inhibits the expression of a molecule that is modulated by 20P1F12/TMPRSS2, classified in class 424, subclass 184.1.

10. Claims 32, 34-35, as solely drawn to a method of inhibiting growth of cancer cells by administering an antibody or fragment thereof that specifically binds to a 20P1F12/TMPRSS2-related protein which inhibits the expression of a molecule that is modulated by 20P1F12/TMPRSS2, classified in class 424, subclass 130.1.

11. Claims 32, 36, as solely drawn to a method of inhibiting growth of cancer cells by administering a vector that comprises a polynucleotide comprising a 20P1F12/TMPRSS2-related protein sequence which inhibits the expression of a

molecule that is modulated by 20P1F12/TMPRSS2, classified in class 424, subclass 93.2.

12. Claims 32, 37, as solely drawn to a method of inhibiting growth of cancer cells by administering a vector that comprises a polynucleotide comprising an antisense polynucleotide complementary to a polynucleotide having a 20P1F12/TMPRSS2-coding sequence which inhibits the expression of a molecule that is modulated by 20P1F12/TMPRSS2, classified in class 424, subclass 93.2, and class 536, 24.5.

13. Claims 32, 38, as solely drawn to a method of inhibiting growth of cancer cells by administering a ribozyme that cleaves a polynucleotide having a 20P1F12/TMPRSS2-coding sequence which inhibits the expression of a molecule that is modulated by 20P1F12/TMPRSS2, classified in class 424, subclass 94.1.

14. Claims 32-33, 39, as solely drawn to a method of inhibiting growth of cancer cells by administering at least one CTL epitope of 20P1F12 which inhibits the expression of a molecule that is modulated by 20P1F12/TMPRSS2, classified in class 424, subclass 184.1.

15. Claims 32-33, 40, as solely drawn to a method of inhibiting growth of cancer cells by administering at least one antibody epitope of 20P1F12 which inhibits the

expression of a molecule that is modulated by 20P1F12/TMPRSS2, classified in class 424, subclass 184.1.

Groups 16-20 have been split based on Claim 41 which is linked to either administering a substance that modulates the status of 20P1F12/TMPRSS2 or is linked to administering a substance that modulates the status of a molecule that is modulated by 20P1F12/TMPRSS2.

16. Claims 41-47, drawn to a method of modulating the status of cancer cells in a mammal comprising administering a substance that modulates the status of 20P1F12/TMPRSS2, wherein said substance is a 20P1F12/TMPRSS2-related protein, classified in class 424, subclass 184.1.

17. Claims 41, 48-55 drawn to a method of modulating the status of cancer cells in a mammal comprising administering a substance that modulates the status of 20P1F12/TMPRSS2, wherein said substance is a antibody or fragment thereof that specifically binds to a 20P1F12/TMPRSS2-related protein, classified in class 424, subclass 130.1.

18. Claims 41, 56, 58-62 drawn to a method of modulating the status of cancer cells in a mammal comprising administering a substance that modulates the status of 20P1F12/TMPRSS2, wherein said substance is a vector comprising a

polynucleotide that comprises a 20P1F12/TMPRSS2 coding sequence, classified in class 424, subclass 93.1.

19. Claims 41, 57 drawn to a method of modulating the status of cancer cells in a mammal comprising administering a substance that modulates the status of 20P1F12/TMPRSS2, wherein said substance is an antisense polynucleotide complementary to a polynucleotide having a 20P1F12/TMPRSS2 coding sequence, classified in class 514, subclass 44.

20. Claims 41, 63 drawn to a method of modulating the status of cancer cells in a mammal comprising administering a substance that modulates the status of 20P1F12/TMPRSS2, wherein said substance is a ribozyme that hybridizes under stringent conditions to the 20P1F12/TMPRSS2 coding sequence, classified in class 424, subclass 94.1.

21. Claims 41-47, drawn to a method of modulating the status of cancer cells in a mammal comprising administering a substance that modulates the status of a molecule that is modulated by 20P1F12/TMPRSS2, wherein said substance is a 20P1F12/TMPRSS2-related protein, classified in class 424, subclass 184.1.

22. Claims 41, 48-55 drawn to a method of modulating the status of cancer cells in a mammal comprising administering a substance that modulates the status of a

molecule that is modulated by 20P1F12/TMPRSS2, wherein said substance is a antibody or fragment thereof that specifically binds to a 20P1F12/TMPRSS2-related protein, classified in class 424, subclass 130.1.

23. Claims 41, 56, 58-62 drawn to a method of modulating the status of cancer cells in a mammal comprising administering a substance that modulates the status of a molecule that is modulated by 20P1F12/TMPRSS2, wherein said substance is a vector comprising a polynucleotide that comprises a 20P1F12/TMPRSS2 coding sequence, classified in class 424, subclass 93.1.

24. Claims 41, 57 drawn to a method of modulating the status of cancer cells in a mammal comprising administering a substance that modulates the status of a molecule that is modulated by 20P1F12/TMPRSS2, wherein said substance is an antisense polynucleotide complementary to a polynucleotide having a 20P1F12/TMPRSS2 coding sequence, classified in class 514, subclass 44.

25. Claims 41, 63 drawn to a method of modulating the status of cancer cells in a mammal comprising administering a substance that modulates the status of a molecule that is modulated by 20P1F12/TMPRSS2, wherein said substance is a ribozyme that hybridizes under stringent conditions to the 20P1F12/TMPRSS2 coding sequence, classified in class 424, subclass 94.1.

26. Claims 64-67, drawn to a method of inducing an immune response comprising exposing cells of the mammal's immune system to an immunogenic portion of a 20P1F12/TMPRSS2-related protein wherein said 20P1F12/TMPRSS2-related protein comprises at least one T cell epitope or at least one antibody epitope and contacting the epitope with a mammalian immune system T-cell or cell capable of producing antibodies, classified in class 424, subclass 184.1.

27. Claims 64, 68-71, drawn to a method of inducing an immune response comprising providing a polynucleotide that encodes a 20P1F12/TMPRSS2-related protein that comprises at least one T cell epitope or at least one antibody epitope, expressing said epitopes, and contacting said epitopes with a mammalian immune system T-cell or cell capable of producing antibodies, classified in class 424, subclass 93.1.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups 2-27 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The invention of Group 1 and the method of Groups 4, 11, 18, 23, and 27 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following

can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polynucleotide product as claimed can be used in a materially different process such as affinity chromatography. The invention of Group 1 and the methods of Groups 2-3,5-10,12-17,19-22,24-26 are not at all related because the polynucleotides of Group 1 are not used in any of the methods of Groups 2-3, 5-10, 12-17, 19-22, 24-26.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Species Election:

Group 16 and 21 (Claims 45-47) are generic to a plurality of disclosed patentably distinct species comprising the following:

a) antigen-presenting cells

b) a CTL polypeptide epitope from 20P1F12/TMPRSS2

c) an antibody epitope from 20P1F12/TMPRSS2

Groups 26 and 27 (Claims 65 and 69) are generic to a plurality of disclosed patentably distinct species comprising the following:

a) a 20P1F12/TMPRSS2-related protein that comprises at least one T-cell epitope that is contacted with a T-cell

b) a 20P1F12/TMPRSS2-related protein that comprises at least one antibody epitope that is contacted with a cell capable of producing antibodies.

The products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues. Additionally, the steps and reagents of the above species are completely distinct and impart different biological functions and uses such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
April 5, 2002

ANTHONY C. CAPUTA
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